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BREAST CANCER AND ENVIRONMENTAL RESEARCH ACT OF 2006

JULY 24, 2006.—Ordered to be printed

Mr. ENZI, from the Committee on Health, Education, Labor, and
Pensions, submitted the following

R E P O R T

[To accompany S. 757]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 757) to amend the Public Health Service Act to authorize the Director of the National Institute of Environmental Health Sciences to make grants for the development and operation of research centers regarding environmental factors that may be related to the etiology of breast cancer, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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I. PURPOSE AND SUMMARY OF THE BILL

S. 757, the Breast Cancer and Environmental Research Act of 2006, does the following:

- Creates a national strategy to conduct research into the possible links between breast cancer and the environment;

- Establishes a peer-reviewed grant program within the National Institutes of Health to fund collaborative Centers that would work across institutions, across disciplines, and with community organizations to study environmental factors that may cause breast cancer; and
- Includes researchers and consumers in an Advisory Panel that will make recommendations on how to determine the grant mechanisms, peer review criteria and, once peer review is conducted, make funding allocation recommendations to the Secretary.

This legislation would authorize the Secretary of Health and Human Services, working through the Director of the National Institutes of Health (NIH), to develop a research program of peer-reviewed grants for the establishment of collaborative Centers of research to study environmental factors that are believed to contribute to the development of breast cancer. The Secretary will establish an Advisory Panel that will: develop a national strategy regarding the collaborative Centers; make recommendations on how to design the grant mechanisms and peer review criteria; and, after peer review has been carried out, make recommendations for allocation of funds to the Centers to prevent unnecessary duplication of research and ensure consistency with the national strategy and its programmatic priorities.

Under a competitive process of peer-reviewed research that includes trained consumers who represent a breast cancer constituency in the decisionmaking process, the NIH Director, in cooperation with the Director of the National Institute of Environmental Health Sciences (NIEHS) and the Director of the National Cancer Institute (NCI), would award grants to conduct multi-institutional and multi-disciplinary research using a broad definition of environment through a national network of collaborative Centers. The bill requires each Center to be multi-institutional and to establish and maintain collaborations at all levels with community organizations in its area of influence, including those community organizations that represent a breast cancer constituency. Each collaborative Center will be required to network with the other funded Centers. Up to eight collaborative, multi-institutional Centers may be funded each year.

II. BACKGROUND AND NEED FOR THE LEGISLATION

Estimates by the American Cancer Society indicate that a woman in the United States has a 1 in 8 chance of developing invasive breast cancer during her lifetime. This risk was about 1 in 11 in 1975. In fact, more women in the United States are living with breast cancer than any other cancer (excluding skin cancer). Approximately 3 million women in the U.S. are living with breast cancer: about 2.3 million have been diagnosed with the disease and an estimated 1 million do not yet know they have it. In 2006, it is estimated that 274,900 new cases of breast cancer will be diagnosed among women in the United States: 212,920 invasive and 61,980 cases of in situ breast cancer. Breast cancer is the second leading cause of cancer death for women in the U.S.; approximately 40,970 women in the U.S. will die in 2006. Breast cancer is the leading cause of cancer death for U.S. women between the ages of 20 and 59, and the leading cause of cancer death for women world-

wide. While breast cancer is about 100 times more common in women, it is important to note that the American Cancer Society estimates that in 2006, about 1,720 new cases of invasive breast cancer will be diagnosed among men in the United States.

Despite these statistics, we still do not know what causes breast cancer. We do know that all women are at risk for breast cancer. We also know that about 90 percent of women who develop breast cancer do not have a family history of the disease. Although scientists have discovered some risk factors for breast cancer, the known risk factors account for only a small percentage (~ 30 percent) of breast cancer cases. There are no proven interventions to prevent breast cancer and there is no cure.

Because many women, and men, have no family history, or known genetic links to breast cancer it is generally believed that the environment plays a role in the development of breast cancer. However, we still do not understand the extent of that role. The committee recognizes the need to create a national strategy to study environmental factors so that we can learn what, if anything, in our environment might be contributing to the breast cancer epidemic and lead to preventive actions.

This legislation came about as a result of two Environmental Policy Summits sponsored by the National Breast Cancer Coalition (NBCC). At the first NBCC Environmental Policy Summit in 1998, more than 50 experts, including scientists, advocates, government officials, and policy-makers, came together to begin developing a strategy for studying the links between breast cancer and the environment. Participants agreed that in order to truly understand what causes breast cancer, and how to prevent it, we must first focus on formulating the right questions. Summit participants emphasized the need to correct the persistent under-funding of research in this important area, while also increasing opportunities for innovative research. NBCC held a second summit in 2000, where more specific recommendations were made in order to accomplish this goal. The Breast Cancer and Environmental Research Act was developed in order to satisfy the recommendations and accomplish the goals set forth at both Summits.

III. LEGISLATIVE HISTORY AND COMMITTEE ACTION

The Breast Cancer and Environmental Research Act was first introduced in the 106th Congress. In 1999 Representative Nita Lowey introduced the bill, and in the Senate it was introduced in 2000 by Senators Lincoln Chafee and Harry Reid. By the end of 2000, the proposed legislation had yielded 16 Senate cosponsors and 98 House cosponsors.

In the 107th Congress, it was reintroduced by Senators Chafee and Reid, and Representatives Lowey and Sue Myrick. In 2001, NBCC advocate Gail Frankel testified at a Senate Environment and Public Works Field Hearing, hosted by Senator Hillary Rodham Clinton and attended by Senators Chafee and Reid, in Garden City, NY regarding the need for such legislation:

We all wonder what causes breast cancer. I, too, have questions about what caused my breast cancer. Diagnosed at 53, I was told that even though my mother died at age 48 from the disease, my breast cancer was unlikely to be

due to an inherited genetic defect since inherited cancer usually shows up at an earlier age in offspring. No other high risk factors applied to me. Did my diagnosis have something to do with where I live? The sad truth is nobody knows; there is no conclusive evidence about what causes this disease.

In 2002, the Senate Labor HHS Appropriations Subcommittee agreed that a strategic approach—like the one taken in this legislation—is needed to study breast cancer and the environment, and included the following language in their committee report:

The committee recognizes the serious lack of research on the relationship between the environment and breast cancer, and believes that it is essential for the Institute to support such research. The committee understands that the Institute will establish a Breast Cancer and Environmental Research Advisory Board to make recommendations to the director with regard to the development of Breast Cancer and Environmental Research Centers. The committee is aware of the tremendous success of the DOD Breast Cancer Research Program and its grant process. The committee expects the Advisory Board to integrate a peer review and planning process along the lines of the DOD integration panel. The committee is pleased that the Advisory Board will include representatives from the breast cancer community who have had breast cancer. The committee further strongly urges the NIEHS to establish centers to conduct multi-disciplinary and multi-institution research on environmental factors that may be related to breast cancer.

The legislation was re-introduced in the 108th Congress by Senators Chafee and Reid, and Representatives Lowey and Myrick. By the end of that Congress, the number of Congressional cosponsors for the Breast Cancer Environmental Research Act increased to 62 in the Senate and 210 in the House. In 2003, the following was included in the fiscal year 2003 Labor-HHS Conference Report language:

The conferees commend NIEHS for its recent efforts to bolster research initiatives on the environmental influences of breast cancer. The conferees recognize the serious lack of research on the relationship between the environment and breast cancer, and believe that it is important for the Institute to support such research. The conferees urge the Institute to establish a group of breast cancer and environmental research advisers to make recommendations to the Director with regard to the support of the breast cancer and environmental research, and to include in the group representatives from the breast cancer community who have had breast cancer. The conferees request an update at the fiscal year 2004 hearings on the progress in establishing an advisory group. The conferees encourage NIEHS to consider establishing centers to conduct multi-disciplinary and multi-institution research on environmental factors that may be related to breast cancer.

In response to the fiscal year 2003 Labor-HHS Conference Report language, NIEHS announced a collaborative program with NCI to fund four research Centers. The specific goal of these Centers is focused on the environmental determinants of puberty and mammary gland development that may increase a woman's risk of breast cancer, which is only one of many questions of interest in this field. Funding for these Centers combined is \$5 million per year over 7 years, for a total of \$35 million. The current Centers do not have an overall national strategy for the field of potential environmental links to breast cancer. Conversely, the strategy developed by the Panel and implemented by the Centers in this legislation will expand the field to all questions that need to be studied to determine any links between the environment and breast cancer.

In the 109th Congress, the legislation was once again re-introduced by Senators Chafee, Reid, Orrin Hatch, Hillary Rodham Clinton, and Jim Talent in the Senate, and by Representatives Lowey, Myrick, Charlie Bass, and Lois Capps. The cosponsorship has reached 65 Senators and 244 Representatives. After accepting a substitute amendment offered by Senator Enzi and cosponsored by Senators Kennedy, Hatch, Clinton, DeWine, Jeffords, Murray, Mikulski, and Reid, the Committee on Health, Education, Labor, and Pensions reported the bill favorably by unanimous voice vote on June 28, 2006.

IV. EXPLANATION OF BILL AND COMMITTEE VIEWS

This legislation is based on the successful Department of Defense Peer Reviewed Breast Cancer Research Program (DOD BCRP), which has been a model program for innovative breast cancer research. The structure of the DOD BCRP was based in large part from recommendations in a report issued by the Institute of Medicine at the request of the U.S. Army. The DOD Program's unique and highly effective structure, its focus on innovation and relevance, its accountability to the public, and its ability to focus on important funding and knowledge gaps, are important characteristics that would be replicated at the NIH through this legislation.

The Breast Cancer and Environmental Research Act includes this effective review structure, involving consumers in the Advisory Panel as well as in peer review. Consumers are defined as educated advocates who represent a constituency of individuals who have had breast cancer. The Panel develops and implements an overall structure that seeks to create a comprehensive strategy for studying the linkage between breast cancer and the environment. When developing this strategy, it is important to include innovative mechanisms and research proposals from a global research community.

Specifically, the Panel's duties would include:

- recommendations for research investment strategy;
- advice on the content and type of solicitation announcements and on the timing and number of solicitations;
- recommendations on proposal format;
- recommendations for review criteria of research proposals to be applied by peer review committees;
- assistance in overall program evaluation;
- budget modifications of proposals recommended for funding;

- recommendations on whether funds should be transferred from one category to another;
- recommendations for selection of proposals for funding by matching scientific merit from peer review with the programmatic goals set for the program; and
- recommendations for dissemination of information on program process.

The Panel would first develop and recommend to the Secretary, a strategy for the grant mechanisms and the peer review criteria. After peer review committees review and score the grant proposals, the Panel would then make recommendations to the Secretary regarding the allocations for the grants, ensuring the grants fulfill the goals of the national strategy. The Panel's recommendations will prevent unnecessary duplication of research and confirm that the grants address a broad range of issues and form the basis of the national strategy. The Panel will be made up of researchers and other health professionals, as well as consumers, who represent organizations of individuals who have had breast cancer.

The Centers, established through the grant process, will be made up of collaborative groups of research scientists from various institutions, and different scientific disciplines as well as community organizations representing individuals with breast cancer who come together to address the issue of exploring the links between breast cancer and the environment. The Centers will develop innovative approaches to study knowledge gaps of research with regard to the environment and breast cancer. Each Center funded by the grants will be expected to collaborate with the other Centers, and to report to the Director of NIH, in order for the highest level of cooperation and accountability to the public and to eliminate unnecessary duplication of research.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 14, 2006.

Hon. MIKE ENZI,
*Chairman, Committee on Health, Education, Labor, and Pensions,
U.S. Senate, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 757, the Breast Cancer and Environmental Research Act of 2006.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Sarah Evans.

Sincerely,

DONALD B. MARRON,
Acting Director.

Enclosure.

S. 757—Breast Cancer and Environmental Research Act of 2006

Summary: S. 757 would amend the Public Health Service Act to authorize the Director of the National Institutes of Health (NIH) to make grants to public or nonprofit organizations to develop and operate centers that would conduct research on environmental factors that may contribute to the development of breast cancer. The

bill also would direct the Secretary of Health and Human Services (HHS) to establish a Breast Cancer and Environmental Research Panel, whose task would be to develop research priorities and make recommendations for the program.

For the activities described above, S. 757 would authorize the appropriation of \$30 million each fiscal year from 2007 through 2012. CBO estimates that implementing the bill would cost \$10 million in 2007 and \$123 million over the 2007–2011 period, assuming the appropriation of the authorized amounts. Enacting S. 757 would have no effect on direct spending or revenues.

The bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 757 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—				
	2007	2008	2009	2010	2011
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Authorization Level	30	30	30	30	30
Estimated Outlays	10	26	29	29	29

Basis of estimate: Two institutes of the NIH, the National Cancer Institute and the National Institute of Environmental Health Sciences (NIEHS), currently support four collaborative Breast Cancer and the Environment Research Centers that study how chemical, physical, and social factors in the environment affect the development of breast cancer. According to officials at NIEHS, those institutes spent approximately \$5 million on those research centers in fiscal year 2005 and plan to spend a similar amount each year through fiscal year 2009. S.757 would provide statutory authorization for similar Breast Cancer and Environmental Research Centers of Excellence administered through the NIH. The bill would authorize those centers for fiscal years 2007 through 2012.

In addition, S. 757 would require the Secretary of HHS to establish within the NIH a nine-member Breast Cancer and Environmental Research Panel, which would set research priorities and make recommendations for the Centers for Excellence program.

For carrying out the above activities, the bill would authorize the appropriation of \$30 million for each of the fiscal years 2007 through 2012. Such authorization would be in addition to any currently authorized appropriations for those activities. For this estimate, CBO assumes that S. 757 will be enacted near the start of fiscal year 2007 and that the authorized amounts will be appropriated for each year. Using historical patterns of spending for similar programs, CBO estimates that implementing the bill would cost \$10 million in 2007 and \$123 million over the 2007–2011 period.

Intergovernmental and private-sector impact: S. 757 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal Costs; Sarah Evans. Impact on State, Local, and Tribal Governments: Leo Lex. Impact on the Private Sector: Jennifer Doleac.

Estimate approved by: Robert A. Sunshine, Assistant Director for Budget Analysis.

VI. APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

S. 757 amends the PHSA to authorize this grant program.

VII. REGULATORY IMPACT STATEMENT

This legislation requires the Secretary, working through the Director of NIH, to establish grants for the development and operation of research Centers regarding environmental factors that may be related to the etiology of breast cancer. The committee has determined that the bill will not have a significant regulatory impact.

VIII. SECTION-BY-SECTION ANALYSIS

Sec. 1. Short title

The Breast Cancer and Environmental Research Act of 2006.

Sec. 2. National Institutes of Health; awards for development and operation of research centers regarding environmental factors related to breast cancer

Instructs the Secretary, acting through the Director of NIH, and working in cooperation with the Directors of NIEHS and NCI to establish a Breast Cancer and Environmental Research Panel and make grants to develop and operate collaborative Centers that would conduct research on environmental factors that may be linked to the development of breast cancer.

Establishes the Breast Cancer and Environmental Research Panel that will be made up of six researchers and other health professionals, and three members from the general public who are breast cancer survivors, or their representatives. The Secretary may choose to include non-voting, ex-officio members as well. The Panel members will elect the Chair of the Panel. The Panel will meet as often as the Director of NIH or the Chair of the Panel determine, but no less than once a year.

The Panel duties include developing a comprehensive strategy regarding collaborative Centers, making recommendations to the Secretary with respect to the mechanisms, peer review criteria, and allocations for the Centers, assisting in the overall program evaluation, and providing recommendations for disseminating information on the process of the program.

The Centers funded by the grants will develop innovative approaches to study unexplored or under-explored areas of the environment and breast cancer. They will also be responsible for identifying key research questions, and knowledge gaps in this area. In addition, the Centers will address key issues regarding environmental factors that may be related to breast cancer, and as a result, contribute to a strategy to address those factors. Each Center must include community organizations in the geographic areas served by the Center that represent individuals with breast cancer. These organizations would be integral collaborators involved at all levels of the decision-making and research in each Center. The Centers will also need to communicate regularly among them-

selves, and, at the direction of the Director of NIH, submit reports on their activities.

The Centers would be funded for up to 5 years. The funding may be extended up to 5 more years after a peer review committee has recommended to the Director of NIH that the Center's funding should be extended. Finally, the Director of NIH will be responsible for ensuring, to the extent practicable, that the Centers are distributed equitably across the country.

Authorization of Appropriations—\$30,000,000 per year for 5 years is authorized by this legislation.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

SEC. 401. * * *

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SEC. 404A. * * *

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SEC. 404G. (a) COOPERATIVE AGREEMENTS AND GRANTS.—

(1) IN GENERAL.—* * *

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SEC. 404H. RESEARCH CENTERS REGARDING ENVIRONMENTAL FACTORS RELATED TO BREAST CANCER.

(a) *IN GENERAL.*—The Secretary, acting through the Director of NIH, based on recommendations from the Breast Cancer and Environmental Research Panel established under subsection (b) (referred to in this section as the 'Panel'), shall make grants to public or non-profit private entities for the development and operation of collaborative, multi-institutional centers for the purpose of conducting multidisciplinary and multi-institutional research on environmental factors that may be related to the etiology of breast cancer. Each such center shall be known as a Breast Cancer and Environmental Research Center of Excellence.

(b) **BREAST CANCER AND ENVIRONMENTAL RESEARCH PANEL.**—

(1) *ESTABLISHMENT.*—The Secretary shall establish within the National Institutes of Health a Breast Cancer and Environmental Research Panel.

(2) *COMPOSITION.*—The Panel shall be composed of—

(A) 9 members to be appointed by the Secretary, of which—

(i) six members shall be appointed from among physicians and other health professionals, who—

(I) are not officers or employees of the United States;

(II) represent multiple disciplines, including clinical, basic, and public health sciences;

(III) represent different geographical regions of the United States;

(IV) are from practice settings, academia, or other research settings; and

(V) are experienced in peer review; and

(ii) three members shall be appointed from the general public who are representatives of individuals who have had breast cancer and who represent a constituency; and

(B) such nonvoting, ex officio members as the Secretary determines to be appropriate.

(3) CHAIRPERSON.—The members of the Panel appointed under paragraph (2)(A) shall select a chairperson from among such members.

(4) MEETINGS.—The Panel shall meet at the call of the chairperson or upon the request of the Director of NIH, but in no case less often than once each year.

(5) DUTIES.—The Panel shall—

(A) develop a comprehensive strategy concerning collaborative centers that would—

(i) result in innovative approaches to study unexplored or underexplored areas of the environment and breast cancer;

(ii) outline key research questions, methodologies, and knowledge gaps concerning environmental factors that may be related to the etiology of breast cancer;

(iii) outline key issues concerning environmental factors that may be related to the etiology of breast cancer; and

(iv) result in an overall strategy to address environmental factors related to breast cancer;

(B) make recommendations to the Secretary with respect to the mechanisms, peer review criteria, and allocations under this section;

(C) assist in the overall program evaluation; and

(D) make recommendations for the dissemination of information on program process.

(c) COLLABORATION WITH COMMUNITY.—Each center under subsection (a) shall include community organizations in the geographic area served by the center, including those that represent women with breast cancer, as integral collaborators involved at all levels of the decision-making and research in such center.

(d) COORDINATION OF CENTERS; REPORTS.—The Director of NIH shall, as appropriate, provide for the coordination of information among centers under subsection (a) and ensure regular communication between such centers, and may require the periodic preparation

of reports on the activities of the centers and the submission of the reports to the Director.

(e) REQUIRED CONSORTIUM—Each center under subsection (a) shall be formed from a consortium of cooperating institutions and community groups, meeting such requirements as may be prescribed by the Director of NIH. Each center shall require collaboration among highly accomplished scientists, other health professionals and advocates of diverse backgrounds from various areas of expertise.

(f) DURATION OF SUPPORT.—Support of a center under subsection (a) may be for a period not exceeding 5 years. Such period may be extended for one or more additional periods not exceeding 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director of NIH and if such group has recommended to the Director that such period be extended.

(g) GEOGRAPHIC DISTRIBUTION OF CENTERS.—The Director of NIH shall, to the extent practicable, provide for an equitable geographical distribution of centers under this section.

(h) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated \$30,000,000 for each of the fiscal years 2007 through 2012. Such authorization is in addition to any other authorization of appropriations that is available for such purpose.

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